NOV 26 2013

K131298

Exactech® Equinoxe® Resurfacing Humeral Head System
Traditional 510(k)

510(k) Summary

Company:	Exactech®, Inc 2320 NW 66th Court Gainesville, FL 32653
Date:	November 14, 2013
Contact Person:	Shing Jen Tai, PhD Sr. Regulatory Affairs Specialist Phone: (352) 327-4638 Fax: (352) 378-2617
Proprietary Name:	Exactech® Equinoxe® Resurfacing Humeral Head System
Common Name:	Humeral Resurfacing
Classification Name:	21 CFR 888.3690 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis Class II
Product Code:	HSD

Legally Marketed Devices to Which Substantial Equivalence Is Claimed

- Biomet Copeland™ MB Resurfacing Humeral Heads (#K010657)
- Tornier Aequalis® Resurfacing Head (#K062661)
- DePuy Global CAP™ Resurfacing Replacement Shoulder (#K031971)
- STD Manufacturing Contoured Articular Prosthetic (CAP) Humeral Head Resurfacing System (#K023096)

Device Description

The Equinoxe Resurfacing Humeral Head System is intended as a cementless humeral resurfacing system that can be used in hemi- shoulder arthroplasty (where it does not articulate with a glenoid component) or total shoulder arthroplasty (where it articulates with a glenoid component). Implantation of this device involves minimal bone removal. The overall design goal of the Equinoxe Resurfacing Humeral Head System is to provide a bone-preserving option for treating degenerative conditions of the shoulder joint.

The Equinoxe Resurfacing Humeral Head System is a modular system, consisting of an articular humeral head component and a humeral cage component mated together via Morse taper connection to provide stabilization of the implant assembly. The dome shaped resurfacing humeral head component is manufactured from cobalt-28Chromium-6Molybdenum alloy per ASTM F1537 with titanium plasma coating per ASTM F1580 and Hydroxylapatite coating per ASTM F1185 on the non-articulating or bone-contacting surface. Manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136) with

titanium plasma coating per ASTM F1580, the cylindrical cage component features multiple fins for anti-rotation. The variable sizing options and the modular composition of the Equinoxe Resurfacing Humeral Head System facilitates selection and anatomic reconstruction of the native humeral head.

If utilized in total shoulder arthroplasty procedures, the System is compatible with the following Equinoxe Shoulder Glenoid components: Keeled Glenoids, Pegged Glenoids, Caged Glenoids, and Augmented Glenoids cleared with the following 510(k)s: K042021, K093430, K113309, K103419, K111379, and K121220.

The Equinoxe Resurfacing Humeral Head System is accompanied by a complete instrumentation and trial system to assist the surgeon in the implantation of each component.

Indications for Use
The Equinoxe Resurfacing Humeral Head System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint where hemi- or total arthroplasty is determined by the surgeon to be the preferred method of treatment. The Equinoxe Resurfacing Humeral Head System is intended for use in patients with the following conditions where the humeral head and neck are of sufficient bone stock and the rotator cuff is intact or reconstructable.

- Osteoarthritis
- Avascular Necrosis
- Rheumatoid Arthritis
- Post-traumatic Arthritis
- Correction of functional deformity
- Fractures of the humeral head

The Equinoxe Resurfacing Humeral Head System is intended for uncemented use only.

Summary of Technological Characteristics
The rationale for substantial equivalence is based on consideration of the following device characteristics:

- *Indications for Use*
  The proposed Equinoxe Resurfacing Humeral Head System and the identified predicates have similar indications for use statements.

- *Materials*
  The proposed Equinoxe Resurfacing Humeral Head System and the identified predicate devices are composed of similar biocompatible materials and coatings, conforming to recognized industry standards for permanent implants.

- *Design Features/Functions*

The proposed Equinoxe Resurfacing Humeral Head System and the cited predicate devices share basic design features and functions.

- *Dimensions*
  The proposed Equinoxe Resurfacing Humeral Head System components and the cited predicate devices are dimensionally comparable.

- *Sterilization*
  The proposed Equinoxe Resurfacing Humeral Head System and the referenced predicate devices are provided sterile for single use only.

- *Performance specifications*
  The Equinoxe Resurfacing Humeral Head System is equivalent to the referenced predicates in that the subject device also withstand clinically relevant biomechanical loads

Non-Clinical Testing

The following mechanical testing, radiographic analysis and cadaveric study were performed to demonstrate that Equinoxe Resurfacing Humeral Head System performs as intended and is substantially equivalent to the identified predicates:

- Radiographic analysis used to determine the appropriate size range of the device that will be most compatible with variability in anatomical fit of native humeral head.
- Cadaveric study conducted to validate that the device can be implanted properly in the expected surgical approach and conditions.
- Joint simulation mechanical testing performed based off ASTM F2028-08 to demonstrate proper fixation/stability of the implant assembly.
- Edge loading mechanical testing completed to show the ability of the implant assembly to withstand the worst-case edge loading conditions.
- Axial pull-off testing conducted to demonstrate readiness and suitability of the taper engagement even after off-axis impaction of the humeral head. This test was conducted per ASTM F2009-00(11).

Substantial Equivalence Conclusion

Based on consideration of indications for use, technological characteristics and results of various mechanical and technical studies described above, it was concluded that Equinoxe Resurfacing Humeral Head System demonstrates substantial equivalence to the identified predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 26, 2013

Exactech, Incorporated
Shing Jen Tai, Ph.D.
Senior Regulatory Affairs Specialist
2320 North West 66th Court
Gainesville, Florida 32653

Re: K131298
Trade/Device Name: Exactech® Equinoxe® Resurfacing Humeral Head System
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
Regulatory Class: Class II
Product Code: HSD
Dated: October 29, 2013
Received: October 30, 2013

Dear Dr. Tai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Equinoxe® Resurfacing Humeral Head System
Traditional 510(k)

Indications for Use Statement

510(k) Number: K131298

Device Name: Exactech® Equinoxe® Resurfacing Humeral Head System

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Prescription Use X **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices